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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/209,799	12/11/98	HERMELING R	X-10242

HM12/0107

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EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	6

DATE MAILED: 01/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/209,799	Hermeling et al.
Examiner	**Group Art Unit**
F. Moezie	1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 02/24/99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-25 is/are pending in the application.

Of the above claim(s) 1-6, 23-25 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 7-22- is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 1-25 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Seq. Listing - Entered

Office Action Summary

Response to Restriction/Election

Applicant's response to the Restriction Requirement and Specie election has been made of record, paper no. 5, dated 12 November 1999.

Applicant's election of Group II invention, claims 7-22, without traverse, is acknowledged. The election of specie on page 5, line 19, is also acknowledged. The claims drawn to non-elected inventions are distinct and would have to be considered on their own merits.

Rejection - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks enabling support for all a GLP-1, a GLP-1 derivative, a DPP-IV protected GLP, a GLP-1 peptide analog and a biosynthetic GLP-1 analog. In fact, there is a considerable degree of diversity between the physical, chemical structure and stability, molecular size and arrangement, polarity, solubility, stereo-chemical, conformational variations and etc. that

each category of compounds mentioned above would have to be tried for crystal formation on its own merits.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-22 are rejected under 35 USC 112, second paragraph as being indefinite in the use of incorrect Markush language. The use of the terminology "a group consisting of " in claim 7, line 2, upon which the rest of the claims depend, followed by "or" on line 4 of the claim is improper. The same holds true for claims 8, 9, 12, 14. Substitution of "and " for "or" is suggested.

Rejection - 35 USC 102 and 103 (a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless --***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 619322 A3 or Kim et al in Pharmaceutical research,, Vol. 12, No 11, pages 1644-1670, 1995.

Either reference teaches that crystalline forms of GLP-1 is known in the art. See the entire documents, especially pages 36-40 of EP and Abstract, page 1667 and Discussion in the article to Kim et al.

Because the claims are drawn to a known subject matter in the art, they are anticipated by and/or rendered obvious in view of the art.

Claims 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 658,568 A1, published 21 June 1995 or EP 619322 published 1994 and further in view of US Patent No. 5,734,026 with an effective date of 24 May 1995.

Each EP reference teaches that crystalline GLP-1 is known in the art. The product, "a crystalline or amorphous suspension, is isolated and purified using standard technics." Page 7, lines 2-10 of '568. The compositions made therefrom and their use are also taught by each reference. See the entire documents.

However, the primary reference does not teach the "standard techniques" for purifying the product.

The secondary discloses the standard method for purification of a polypeptide using ethanol as a solvent in a buffer such as citrate buffer wherein "The formation of crystals depending on time, pH and temperature" col. 2, lines 50+. See the entire document.

Because the conditions for crystallization and purification of GLP-1 is taught by the art one of ordinary skill in the art at the time the invention was made would have been motivated to purify the product of the primary reference (for its extended release time) by the method(s) of the secondary reference to obtain a purified product with reasonable expectation of success. Moreover, since the conditions for crystallization as taught by the art are substantially the same as in the instant application, it would have been expected to obtain the same crystalline shape(s). In addition, the use of the crystals in compositions for the purposes of treating a patient would also have been obvious at the time of the invention in view of the art.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-16 and 27-34 of U.S. Patent No. 5,977,071. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is disclosed in the patent and is covered by the patent, ie GLP-1in crystalline form.

Claims 7-22 are not allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. Christopher Low (SPE) at 308-2923.

F. T. MOEZIE, PH.
PRIMARY EXAMINER
ART UNIT 1653